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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,186	02/01/2000	John McMichael	13024/35946	4501

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/495,186	MCMICHAEL ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 10-4-07 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 and 20 have been canceled. Claims 15-19 remain pending and under consideration.

Claim Rejections - 35 USC § 112

Claims 15-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Claim 15 requires treating a patient having pain caused by otitis media comprising the steps of: administering eardrops to the ear of said patient in a manner so as not to effect gene transfer, thereby reducing said pain, wherein said eardrop comprises an effective amount of DNA in a pharmaceutically-acceptable vehicle.

Otitis media is caused by bacteria or viruses in the ear and results in tympanic membrane retraction, bulging, redness and immobilization (Klein of record, 1994, Clinical Infectious Disease, Vol. 19, pg 823-833). Treatment with analgesic and decongestants do not alter the course of the infection, as neither have an effect on the bacteria or virus causing the disease. Thus, the person of skill in the art would conclude

that the only management methods for treating otitis media itself, and not just symptoms of otitis media, are those that result in the reduction of bacteria or virus numbers. The prior art taught that even administering placebo to patients having otitis media results in decreasing the number of bacteria. Dagen of record (1988, Ear, Nose and Throat J., Vol. 77, pg 16-19) taught administering placebo to patients with otitis media caused by *H. influenza* resulted in a decrease in 48% of the bacteria present. Administering placebo to patients with otitis media caused by *S. pneumococcus* resulted in a decrease in 16% of the bacteria present. Examples XX, XXI, XXIV and XXV are directed to the treatment of pain; however, the specification does not evidence in these examples, or elsewhere in the disclosure the reduction in the number of bacteria or virus which cause otitis media. Nor do the examples have controls that teach obtaining results better than a placebo effect. Thus, applicants have not provided evidence of patients receiving treatment results in the decrease in the number of bacteria or virus or that the results obtained are greater than a placebo effect. Furthermore, it is reasonable to assume that the ear of an individual already has DNA in the fluid within the ear as viral and bacterial particles contain DNA. However, the specification does not provide adequate guidance indicating that the minute amount of DNA being added in the eardrop is effecting a change in the symptoms or the amount of pathogen in the ear. Therefore, it would require one of skill undue experimentation to obtain a therapeutic effect against otitis media that is a direct result of administering eardrops containing DNA.

Applicants' arguments state the basis of the rejection is that the disclosure fails to enable reducing bacteria or virus numbers. Applicants' statement misses an important

aspect of the rejection. The rejection is also based on the fact that observed effect may be a placebo effect because applicants did not use adequate controls.

Applicants argue the method claims is not antibacterial. Applicants' argument is not persuasive. The claims encompass treating otitis media caused by bacterial infections, especially in view of the definition of otitis media provided by applicants that states otitis media is caused by viral or bacterial infection and results in inflammation. Overall, the specification does not provide evidence that the method claimed reduces the number of bacteria or virus or provide any controls indicating the method claimed provides anything more than a placebo effect.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner